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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL COMPANY,  
INC., et al.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

Civil Action No. 3:09-cv-5421 (GEB) (TJB)

**DEFENDANT WEST-WARD  
PHARMACEUTICAL CORP.'S  
STATEMENT OF UNDISPUTED  
MATERIAL FACTS IN SUPPORT OF  
ITS MOTION FOR SUMMARY  
JUDGMENT**

Defendant West-Ward Pharmaceutical Corp. ("West-Ward"), pursuant to Local Civil Rule 56.1, respectfully submits this, its Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment ("Statement of Facts"). West-Ward submits this Statement of Facts and the corresponding Motion for Summary Judgment in support of its theory that Plaintiffs' unclean hands bar them from obtaining the relief they seek.

**STATEMENT OF UNDISPUTED MATERIAL FACTS**

1. Plant extracts containing colchicine have been used to treat gout for more than two thousand years, and colchicine in its isolated form has been utilized to treat and prevent gout since the late 1800s. (Pls.' Compl. [Doc. No. 1] ¶ 59.)

2. West-Ward is the leading supplier of colchicine tablets in the United States, and has sold more than a billion colchicine tablets since 1972. (Declaration of Michael Raya in Support of Defendant West-Ward Pharmaceutical, Corp.'s Motion for Summary Judgment. ("Raya Decl."), ¶ 5.)

3. The United States Food and Drug Administration ("FDA") is aware that West-Ward manufactures and distributes colchicine tablets, having inspected the plant where West-Ward's colchicine is manufactured at least 27 times since 1995, and listing West-Ward's colchicine tablets in its National Drug Code ("NDC") Directory under NDC 00143-1201 for at least thirty years. (Raya Decl. ¶¶ 6, 7.)

4. The FDA has never questioned West-Ward's authority to manufacture or distribute colchicine tablets without formal FDA approval, despite being aware of West-Ward's activities. (Raya Decl. ¶ 7.) West-Ward has never received a Warning Letter or other communication from the FDA telling West-Ward to stop manufacturing, marketing, or distributing its colchicine tablets. (*Id.* ¶ 8.)

5. West-Ward is a generic drug company, and does not market, advertise or promote its colchicine tablets in the customary sense of those terms. (Raya Decl. ¶ 9.) The only "promotional" materials distributed by West-Ward relating to its colchicine tablets are catalogs containing a list of available drugs and corresponding prices. (*Id.* ¶ 10.)

6. West-Ward's colchicine tablets appear on some Wholesaler Ordering Systems and Price Lists as those terms are defined in Mutual's Complaint. (Raya Decl. ¶ 10.)

7. The only information about West-Ward's colchicine tablets that generally appears on the Price Lists and Wholesaler Ordering Systems is the product name, strength, package size, National Drug Code, price, and manufacturer. (Raya Decl. ¶ 11.)

8. Occasionally, the Price Lists and Wholesaler Ordering Systems will also report Therapeutic Equivalency Ratings, as published in FDA's Orange Book of Approved Drug Products. Because West-Ward's colchicine tablets are not approved by FDA, this field is filled in with "N/A" (not applicable) or "NR" (not rated). (Raya Decl. ¶ 12.)

9. West-Ward is unaware of any Wholesaler Ordering System or Price List that has ever represented West-Ward's colchicine tablets as FDA approved. (Raya Decl. ¶ 13.)

10. Plaintiff Mutual Pharmaceutical Company, Inc. is a subsidiary of URL Pharma, Inc., and an affiliate to United Research Laboratories, Inc. (*See* Declaration of Jared M. Lina in Support of Defendant West-Ward Pharmaceutical, Corp.'s Motion for Summary Judgment ("Lina Decl."), ¶ 4, Tab 1.) Hereinafter, the term "Mutual" shall mean all or any of Mutual Pharmaceutical Company, Inc., URL Pharma, Inc., and United Research Laboratories (a/k/a URL).

11. In the current lawsuit, Mutual alleges that the appearance of Defendants' colchicine tablets on Wholesaler Ordering Systems and Price Lists "constitute[s] false and misleading descriptions or representations of fact that their colchicine products are safe, effective and/or FDA approved, and that the safety and warning information provided with Defendants' unapproved colchicine products is complete." (Pls.' Compl. [Doc. No. 1] ¶ 143.)

12. Mutual also distributed more than 100,000,000 0.6 mg colchicine tablets without FDA approval from 1993 until July 2006 in direct competition with the Defendants in this lawsuit. (Raya Decl. ¶ 14, ; Lina Decl., **Tab 2** (at ¶ 5), **Tab 3** (at ¶ 3); Objections and Responses of Pls. to Def. West-Ward Pharmaceutical Corp.’s First Set of Requests for Admis. No. 6.)<sup>1</sup>

13. Mutual utilized the same Price Lists and Wholesaler Ordering Systems that it accuses West-Ward of using in the Complaint to market its unapproved colchicine tablets. (*See* Objections and Resps. of Pls. to Def. West-Ward Pharm. Corp.’s Second Set of Interrogs. Nos. 17, 19 (identified by West-Ward as Nos. 16(b) and 16(d)); *see also* Objections and Responses of Pls. to Def. West-Ward Pharmaceutical Corp.’s First Set of Requests for Admis. Nos. 8-11); Lina Decl., **Tab 2** (at ¶ 5); **Tab 4** (MUTUAL\_272788 [Rows 59, 60]); **Tab 5** (MUTUAL\_871428 [Rows re: Colchicine]); *See also* Declaration of Eric Cardinal (“Cardinal Decl.”), ¶¶ 5, 6, Ex. A [WKM 0516, WKM 0519, WKM 0522].)

14. The Wholesaler Ordering Systems and Price Lists reported the same categories of information for Mutual’s unapproved colchicine tablets that appear for West-Ward’s tablets (*i.e.* product name, strength, package size, label and its unapproved package insert, NDC number, pricing and manufacturer). (Objections and Resps. of Pls. to Def. West-Ward Pharm. Corp.’s Second Set of Interrogs. Nos. 16 & 18 (identified by West-Ward as Nos. 16(a) and 16(c).))

15. Mutual also alleges in its Complaint that the “safety and warning information provided with Defendants’ unapproved colchicine products” falsely represents that “their colchicine products are safe, effective and/or FDA approved.” (Pls.’ Compl. [Doc. No. 1] ¶ 143.)

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<sup>1</sup> Plaintiffs’ Responses and Objections to West-Ward’s Second Set of Interrogatories and First Requests to Admit were filed with the Court contemporaneously with West-Ward’s Motion for Summary Judgment.

16. However, between 1993 and 2006, Mutual distributed the same colchicine tablets that Defendants West-Ward and Excellium Pharmaceutical, Inc. (“Excellium”) distributed, purchasing more than 170,000,000 colchicine tablets directly from West-Ward and Excellium for distribution under Mutual’s own label, and using the same prescribing information, with the same safety and warning information provided with West-Ward’s and Excellium’s unapproved colchicine product. (Raya Decl. ¶¶ 14, 15, 17; Lina Decl., **Tab 2** (at ¶ 5), **Tab 6**.)

17. Mutual’s unapproved 0.6 mg colchicine tablets were priced at approximately \$.09 per tablet. (Lina Decl., **Tab 3** (at ¶ 4).)

18. In its Complaint, Mutual also alleges that “relevant consumers are likely to mistakenly believe that the ‘NR’ or ‘N/A’ rating means that their unapproved colchicine products do not need to be approved by the FDA in order to be sold lawfully.” (Pls.’ Compl. [Doc. No. 1] ¶ 111-112.)

19. Just a few years prior to filing suit, Mutual provided the same “NR” rating for its unapproved colchicine products to McKesson, one of the country’s largest wholesalers. *See* Lina Decl., **Tab 7** (MUTUAL\_000274661-62 [Rows 22 and 43]), **Tab 8** (MUTUAL\_000267128 [Row 116]).

20. Mutual also stated on its own website that its unapproved colchicine tablets had an “NR” rating as recently as November 2006. (Lina Decl., **Tab 9** (at ¶¶ 3-4, Ex. 2).)

21. Mutual reportedly ceased distributing unapproved colchicine tablets in 2006, but Mutual’s unapproved colchicine tablets remained on the market until at least 2009. (Lina Decl., **Tab 10** (MUTUAL\_001658023 through 001658031 [showing monthly sales of URL’s unapproved colchicine tablets from October 2006 through July 2008]), **Tab 11**

(MUTUAL\_000235494 [February 3, 2009 email from Plaintiffs' Advertising and Sales Support Manager stating "**REDACTED**"])).)

22. Mutual's unapproved colchicine tablets appeared on McKesson Corporation's Wholesaler Ordering System and Red Book's Price List until at least 2009. (Lina Decl., Tab (See App., **Tab 12** (MUTUAL\_000233436 [**REDACTED**]), **Tab 13** (MUTUAL\_000235368 [**REDACTED**]), **Tab 14** (MUTUAL\_001399059 [**REDACTED**])).)

23. As of July 7, 2010, Mutual's unapproved colchicine tablets still appeared on the Medi-Span Price List, which still contained essentially the same information as reported for West-Ward's tablets, including an "NR" Therapeutic Equivalency Rating. (See Cardinal Decl., ¶¶ 5, 6, Ex. A. [WKM 0516; WKM 0519; WKM 0522])) Mutual's unapproved tablets appear on the Medi-Span Price List under NDC 00677-1962, which is the same NDC number assigned to Mutual's unapproved tablets in 2006. (*Id.*)

24. Mutual recently shifted away from selling unapproved or generic drugs, and modified its business model to seek FDA approval for well-established drugs that for one reason or another had never been approved by FDA. (See Lina Decl., **Tab 15** (MUT\_000341596 [URL Confidential Information Memorandum stating that "[t]he core elements of the Company's product development strategy are . . . to focus on existing, well-known compounds minimizing development risk and cost. . . ."])).)

25. Mutual pursued this strategy because a "high level of profitability is possible because, unlike traditional branded pharmaceutical products, URL Pharma's model targets products that have well-known therapeutic indications thereby minimizing development, commercialization, and marketing expenses." (Lina Decl., **Tab 15** [MUTUAL\_000341611]).)

26. The other two plaintiffs in this action, AR Holding Company, Inc. and AR Scientific, Inc., were created by Mutual's parent company, URL Pharma, Inc., at or about the time of Mutual's shift in business strategy. (Lina Decl., Tab 1). Mutual, AR Holding Company, Inc., and AR Scientific, Inc. are collectively referred to herein as "Plaintiffs."

27. In August 2005, Plaintiffs obtained FDA approval for quinine sulfate, a drug that had been sold for years without FDA approval. When the FDA did not take immediate action against the sale of unapproved quinine sulfate following Plaintiffs' approval, Plaintiffs filed a lawsuit in the Central District of California, asserting, *inter alia*, claims of unfair competition and false advertising against the distributors of unapproved quinine sulfate. (*See Mutual Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925 (C.D. Cal. 2006) (hereinafter, the "*Ivax* Litigation."))

28. The *Ivax* Court granted Plaintiffs' motion for preliminary injunction, at the same time noting that the FDA's primary jurisdiction was "the only argument raised by defendants as to why Mutual lacks a probability of success on this claim." (*Id.* at 939.)

29. On September 30, 2008, Plaintiffs submitted to the FDA a New Drug Application ("NDA") for their 0.6 mg colchicine tablets. (*See* Pls.' Compl. [Doc. No. 1] ¶ 7.)

30. Immediately after submitting their NDA to the FDA – and prior to obtaining the FDA's approval – Plaintiffs began lobbying the FDA to take immediate action against distributors of unapproved colchicine tablets, including West-Ward. (Lina, Decl., **Tab 16** [email chain between Plaintiffs and FDA].)

31. Plaintiffs' ability to realize their business goals with respect to colchicine depended on whether the FDA elected to take prompt action to remove unapproved colchicine tablets from the market, and Plaintiffs acknowledged that one of the risks of their new business

strategy was that the FDA would not act quickly. (*See* Lina Decl., **Tab 17** (MUTUAL\_000315723 [REDACTED]); **Tab 18** (MUTUAL\_000232595 [REDACTED]); **Tab 19** (MUTUAL\_000235997 [REDACTED]).)

32. Plaintiffs have acknowledged that “[o]nly the FDA has the authority to remove unapproved colchicine from the market.” (Lina Decl., **Tab 20** (MUTUAL\_000192629 [Answer to Question No. 2 in Plaintiffs’ internal literature]).).

33. In their marketing literature, Plaintiffs stated that they had a back-up “legal strategy” to remove unapproved colchicine tablets from the market in the event that the FDA did not take enforcement action against unapproved colchicines tablets. (Lina Decl., **Tab 21** (MUTUAL\_000237324 [REDACTED]), (MUTUAL\_000237325 [REDACTED]); **Tab 22** (MUTUAL\_000237082 [REDACTED]); **Tab 23** (MUTUAL\_000236469 [REDACTED]); **Tab 24** (MUTUAL\_000236799 [REDACTED]).)

34. Plaintiffs obtained FDA approval for their colchicine tablets, called Colcrys, on or about July 29, 2009 and immediately began distributing their product at a price of \$4.85 per tablet. The price for Colcrys was an approximately 5000% increase in price from the \$.09 colchicine tablets that Mutual sold only a few years earlier. (Lina Decl., **Tab 25**.)

35. Plaintiffs were cognizant of the potential public backlash that was likely to result from their new business model. (Lina Decl., **Tab 18** (MUTUAL\_000232595 [REDACTED]), **Tab 26** (MUTUAL\_000000647768 [REDACTED]).)

36. Public criticism surrounding Plaintiffs’ attempt to monopolize the colchicine market has been well documented nationally, and public displeasure has been shared directly with the FDA. (*See* Lina Decl., **Tabs 27-32**.)

37. In the wake of this public criticism and the quadruple digit percentage increase in price for colchicine tablets, the FDA has not taken any enforcement action against West-Ward's unapproved colchicine tablets. (*See* Raya Decl. ¶ 8.)

38. FDA's inaction with respect to West-Ward's sales of colchicine tablets is consistent with its published and clearly defined policies. (*See* ¶¶ 39 through 41, *infra*.)

39. In 2008, the FDA took formal enforcement action against the *injectible* form of colchicine, removing it from the market entirely. (Lina Decl, **Tab 33**) In the corresponding Federal Register notice, the FDA expressly noted that the *oral* form of colchicine is substantially safer than the *injectible* form, stressing that "[t]his notice does not affect the legal status of products containing colchicine in oral dosage forms, which FDA intends to address at a later date." (*Id.* (bottom of p. 4.))

40. The FDA also posted on its website that: "FDA is not taking any orally administered colchicine products off the market at this time, whether approved or unapproved." (**Tab 34** [response to Question No. 5].)

41. In addition, the FDA published a Marketed Unapproved Drugs -- Compliance Policy Guide in 2006, which discusses how FDA will exercise its discretion in situations such as this, stating:

When a company obtains approval to market a product that other companies are marketing without approval, FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (e.g., seizure or injunction) against marketed unapproved products of the same type. However, the grace period provided is expected to vary from this baseline based upon the following factors: (1) the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of the holder of the approved application to meet the needs of patients taking the drug); (2) whether the effort to obtain approval was publicly disclosed; (3) the difficulty associated with conducting any required studies, preparing and submitting applications, and obtaining approval of an application; (4) the burden on affected

parties of removing the products from the market; (5) the Agency's available enforcement resources; and (6) any other special circumstances relevant to the particular case under consideration.

(Lina Decl., **Tab 35** (at p. 6).)

42. In the months following the FDA's approval of Colcrys, Plaintiffs pressed the FDA to take immediate enforcement action against unapproved colchicine tablets. (Lina Decl., **Tab 36-38, Tab 39** (MUTUAL\_000028142 [REDACTED]), **Tab 40** (REDACTED).)

43. Rather than wait for the FDA to take action against the distributors of unapproved colchicine, Plaintiffs initiated their backup "legal strategy," seeking relief from the United States District Court for the Central District of California, the same district court in which a preliminary injunction in the *Ivax* case was granted. (*See generally*, Pls.' Compl. [Doc. No. 1].)

44. Plaintiffs filed an Emergency Motion for Preliminary Injunction in the present lawsuit against Defendants on September 11, 2009, seeking to enjoin Defendants from marketing, selling, and/or distributing their colchicine tablets. (Pls.' Notice of Mot. and Mot. for Prelim. Inj. [Doc. No. 50].)

45. Unlike the defendants in *Ivax*, who had only defended the motion on the ground of FDA primary jurisdiction, West-Ward challenged the merits of Plaintiffs' false advertising claims, presenting survey evidence to prove that it did not cause any confusion that might exist in the marketplace, and that Plaintiffs' unclean hands barred them from the relief they are seeking. (*See* Court Order dated October 19, 2009 [Doc. No. 139], holding that "[h]ere, however, Defendants have not just relied on the primary jurisdiction doctrine. They also attack the merits of Plaintiffs' false advertising claim, the sufficiency of the evidence presented by Plaintiffs, and the equities of enjoining Defendants from engaging in the very same behavior that Plaintiffs were also engaged in until days before they commenced this litigation.")

46. The California Court denied Plaintiffs' Motion on October 19, 2009 holding, *inter alia*, that:

- "[T]his Court is reluctant to view the Lanham Act's false advertising provisions as broadly as did the Ivax court."
- "[T]he Court is not convinced that having drugs listed on a Price List or drug ordering system maintained by a third party even constitutes a 'false statement' in 'commercial advertising or promotion' to fall within the scope of the Lanham Act's false advertising provisions."
- "Moreover, there is little evidence that Defendants have in any way created the confusion experienced by pharmacists, or that this confusion is limited to colchicine products."
- "Plaintiffs' contentions concerning the product labels and inserts are even weaker, both because the evidence of confusion is weaker and because disputes concerning the content of those labels and inserts falls even more squarely within the primary jurisdiction of the FDA."

(*See* Court Order dated October 19, 2009 [Doc. No. 139].)

47. The California Court also noted that "the evidence indicates that almost up to the moment they commenced this action, [Plaintiffs] were engaged in precisely the same activity over which they now seek to enjoin their competitors." *Id.*

48. The California Court concluded that "the doctrine of unclean hands substantially decreases the likelihood that Plaintiffs will ultimately prevail on the merits." *Id.*

49. In addition, the California Court transferred the lawsuit to this District. *Id.*

50. In the days, weeks, and months after Plaintiffs' Motion for Preliminary Injunction was denied, Plaintiffs sent another round of letters to the FDA, again urging the agency to take immediate enforcement action against unapproved colchicine tablets. (Lina Decl., **Tabs 41, 42.**)

51. To date, the FDA has not taken any steps to remove West-Ward's colchicine tablets from the market. (Raya Decl. ¶ 8.)

52. On April 29, 2010, FDA issued a warning letter to Defendant Vision Pharma, LLC against its continued distribution of colchicine tablets. (Lina Decl., **Tab 44.**) That letter followed a warning letter sent a few months earlier to Vision's manufacturer, Sunrise Pharmaceutical, Inc., in which FDA accused Sunrise of numerous GMP (good manufacturing practices) violations. (*Id.* at **Tab 43.**)

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